UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

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| DIALYSIS PATIENT CITIZENS, *et al.*, | ) | |
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| Plaintiffs, | ) | |
| | ) | |
| v. | ) | No. 4:17-cv-00016-ALM |
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| SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al.*, | ) | |
| | ) | |
| Defendants. | ) | |
| | ) | |

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

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## INTRODUCTION AND SUMMARY

Patients with end-stage renal disease ("ESRD") face daunting medical needs and costs, including either a regular course of dialysis or a transplant in order to survive. Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment, Interim Final Rule with Comment Period, 81 Fed. Reg. 90211, 90211 (Dec. 14, 2016) ("Interim Rule").

Several options exist to pay for the extraordinary health care needs of ESRD patients. Original fee-for-service Medicare, a program with a wide variety of participating providers, is usually available only to persons age 65 or older. But an ESRD patient with as few as six quarters of covered employment can obtain such Medicare entitlement regardless of age. 42 U.S.C. § 426-1. Patients with limited incomes and assets may also be eligible for participation in the comprehensive health services offered under the Medicaid program, and many patients are entitled to benefits under both Medicare and Medicaid. 81 Fed. Reg. 90213. ESRD patients may also be eligible to enroll in private health plans, such as group health plans offered by an employer or plans available to individuals in the individual market. *Id.*

A dialysis facility may be paid about $100,000 more per year for one patient enrolled in a commercial health insurance plan, compared to what the facility would receive for the same services rendered to a patient enrolled under a public program (Medicare and/or Medicaid). *Id.* at 90214. The facility therefore stands to "gain financially" by making, either directly or through another entity, "a relatively small outlay to pay the individual's premium to enroll in commercial coverage" because it will receive much more in reimbursement for an identical set of health care services. *Id*. at 90214-15. Unsurprisingly, as commenters on all sides noted in the rulemaking, dialysis facilities do indeed arrange to pay for individual market premiums. *Id.* at 90214. For the *provider*'s bottom line, commercial coverage is often the best choice.

But commercial coverage is often not the best choice for the *patient*; indeed, as the Centers for Medicare & Medicaid Services ("CMS") found, it can be a choice that makes it harder for a patient to get a kidney transplant and leads to mid-year disruptions in coverage for patients for whom continuity of coverage is especially critical. *Id.* at 90215. Unfortunately, the main source of information for a patient faced with choosing what coverage option best fits his or her unique circumstances is often an agent of the dialysis facility. *See* Pls.' Ex. D ¶ 25, ECF No. 3-21 (patient selects a plan "following consultation with his or her social worker or other advisor provided through his or her renal care provider"). And the provider has an enormous financial conflict of interest given the boost to its bottom line that accrues from every patient who can be steered into choosing a commercial plan. Even where a provider (or a provider-funded charity) makes payment of a patient's premium, the choice that is right for the provider may be wrong for the patient.

The Interim Rule that plaintiffs challenge here is a limited and modest but urgently needed step to protect these vulnerable patients by providing greater transparency in the choice of coverage. As an interim measure while CMS considers whether to ban third party premium payments from providers altogether, the Interim Rule promotes disclosure in two ways. First, facilities must inform patients on a timely basis of their coverage options, including the financial risks and benefits of different plans; facilities must provide information about premium assistance; and facilities must, in effect, disclose their conflict of interest, noting both subsidies provided for enrollment in individual market health plans and the reimbursements the facilities expect to receive as a result of such subsidization. 81 Fed. Reg. 90227-28. Second, facilities must disclose to issuers of individual market plans when they are making, either directly or through another entity, payments of premiums and either obtain assurance that the issuer will accept such payments or take reasonable steps to assure that such payments are not made. *Id.* at 90229.

The agency had good cause and reason to implement these transparency rules on an interim basis. The agency received evidence in response to its August 2016 request for information which showed that the "widespread practice of third parties making payment of premiums for individual market coverage places dialysis patients at significant risk of three kinds of harms: Having their ability to be determined ready for a kidney transplant negatively affected, being exposed to additional costs for health care services, and being exposed to significant risk of a mid-year disruption in health care coverage." *Id.* at 90221. It is no wonder that the agency concluded that "delay caused by" waiting for further rulemaking proceedings would have created "unacceptable risks to patient health." *Id*.

The agency's expert judgment on these issues should not be disturbed, let alone cast aside through the extraordinary remedy of a temporary restraining order. For the reasons amply stated in the Interim Rule, the agency had good cause to act and to act promptly. There is thus little or no likelihood that plaintiffs will prevail on their challenges to the Interim Rule. The balance of hardships and the public interest also favor upholding the transparency requirements of the Interim Rule. To be sure, the providers' bottom lines may be harmed by greater transparency about their practices of steering patients to commercial insurance, and there may be some individual patients who might be better off financially if their insurers can be kept in the dark about the source of premium payments on their policies. But the agency's judgment that disclosure of the truth about providers' payments of premiums will avoid harm to the overall community of patients and to the public interest weighs more heavily and decisively. In this area, honesty should be the best policy.

Perhaps recognizing the weakness of their conventional arguments against the Interim Rule's disclosure requirements, plaintiffs suggest at the very outset of their brief (and every ten pages thereafter) that the Interim Rule is somehow invalid because it was issued shortly before a

change of administration, with plaintiffs speculating that the incoming administration might have different views. Pls.' Br. 1, 10-11 & n.7, 21, 31, ECF No. 3. But a transition period is not a holiday for wrongdoing in which agencies are powerless to address harms that have come to their attention and require regulatory correction. Moreover, any incoming administration will have much on its plate in its first few months in office. An outgoing administration that punts on matters requiring immediate attention, leaving them to further clog an incoming administration's docket, does no favors for its successor. If it turns out that the new administration does wish to implement a different policy, it may do so even if the prior administration has acted. *E.g.*, *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005). This is particularly the case here, where the agency has issued only an *Interim* Final Rule *With Comment Period* that already expressly contemplates that the agency will consider new views and perspectives before issuing any permanent rule. Thus, plaintiffs' attempt to politicize this dispute is nothing but a red herring. The new administration already has the power to apply its policies through the rulemaking process, and this case concerns only the rule that governs in the meantime.

## STATUTORY AND REGULATORY FRAMEWORK

Congress has generally entrusted the Secretary of Health and Human Services, through CMS, to administer the Medicare program. *See* 42 U.S.C. § 1395hh(a)(1). Dialysis is no exception. Congress mandated extensive protections for ESRD patients, *see* 42 U.S.C. § 1395rr, and empowered CMS to promulgate further protections by regulation in the form of "conditions." *Id.* § 1395hh(b)(1); *see also id.* § 1395hh(a)(1). It has done so. *See* 42 C.F.R. pt. 494; *id.* §§ 488.1 *et seq.*

Pursuant to this statutory authority, CMS has promulgated a comprehensive set of health and safety standards addressing every aspect of dialysis treatment, from a beneficiary's choice of

dialysis facility to the qualifications of the employees who care for her to her ultimate discharge. In some cases, the standards are broad indeed. For example, the regulations require that dialysis facilities "protect and provide for the exercise of" patients' rights to "[r]espect," "dignity," and "privacy and confidentiality in all aspects of treatment." 42 C.F.R. § 494.70(a)(1), (3). In other cases, the regulatory requirements are more specific. For example, the agency's "Patients' rights" regulation mandates that facilities provide disclosures to each patient regarding fourteen distinct topics, from alternative treatment settings to cost sharing requirements (costs borne by the patient, not Medicare). *Id.* § 494.70(a)(5)-(17), (b)(1). This case involves two new, interim requirements, including one creating another patient disclosure requirement.

## STATEMENT OF THE CASE

### A. Insurance Options for ESRD Patients

ESRD "is a kidney impairment that is irreversible and permanent." 81 Fed. Reg. 90212. "People with ESRD require either a regular course of dialysis or kidney transplantation in order to live." *Id.* "Given the high costs and absolute necessity of transplantation or dialysis for people with failed kidneys, Medicare provides health care coverage to qualifying individuals diagnosed with ESRD, regardless of age." *Id.*; *see* 42 U.S.C. § 426-1. Although individuals under 65 eligible for Medicare due to ESRD cannot ordinarily enroll in Medicare Advantage at present, original fee-for-service Medicare, with its wide and comprehensive array of participating providers, is available to cover kidney transplantation, maintenance dialysis, and other health care needs of ESRD patients. 81 Fed. Reg. 90212.[1] As a result, "Medicare is the predominant payer of ESRD services in the United States, covering (as primary or secondary payer) about 88 percent of the

[1] In addition, basic Medigap policies are available to ESRD patients under 65 in more than half the states, including Texas. 81 Fed. Reg. 90212 n.1.

United States ESRD patients receiving hemodialysis in 2014." *Id.*

"In addition to Medicare, Medicaid provides coverage for some people with ESRD. Many individuals enrolled in Medicare may also qualify for full benefits under the Medicaid program on the basis of their income, receipt of Supplemental Security Income, being determined medically-needy, or other eligibility categories under the State Plan. In addition, low income individuals enrolled in Medicare may qualify for the Medicare Savings Program under which the state's Medicaid program covers some or all of the individual's Medicare premiums and, for some individuals, Medicare cost-sharing. Finally, some individuals who are not eligible for enrollment in Medicare may qualify for Medicaid." *Id.* at 90212-13.

Although Medicaid programs do not typically have as comprehensive a network of providers as fee-for-service Medicare (neither, of course, do many private plans that offer limited networks of preferred providers, *id.* at 90216), Medicaid programs are designed "to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396a(a)(30)(A). For patients who can receive Medicaid, "the health care costs for which they are financially responsible are negligible—and many face no cost-sharing or premiums at all." 81 Fed. Reg. 90216. Fully half of ESRD patients under 65 who are enrolled in Medicare are also entitled to benefits under Medicaid. *Id.* at 90213. Such "dual eligibles" can enjoy both the broad network of providers available under Medicare and the Medicaid program's contribution to, or elimination of, cost-sharing requirements that Medicare-only patients may face.

Finally, patients with ESRD may be eligible for commercial coverage, either through a group health plan sponsored by an employer or through their state's individual marketplace, including (but not limited to) a qualified health plan ("QHP") available on an exchange set up

under the Affordable Care Act ("ACA"). *Id.* However, if a patient is enrolled in Medicare, it is (with some exceptions) unlawful to knowingly sell or issue a health insurance policy that duplicates the benefits the patient is entitled to under Medicare. 42 U.S.C. § 1395ss(d)(3)(A)(i); 81 Fed. Reg. 90213; *see also* 81 Fed. Reg. 94058, 94067-68 (Dec. 22, 2016) (Medicare anti-duplication provision).

As plaintiffs' affiant from the American Kidney Foundation ("AKF") explains, Pls.' Ex. D ¶ 25, each of these "coverage option[s] has its own unique benefits and drawbacks, just as each ESRD patient's personal circumstances are unique," and thus which option will be best suited to a given patient will vary depending on those circumstances.

### B. Patient Choice of Coverage Options and Dialysis Facilities' Conflicts of Interest

Although which coverage option is best for the patient varies with each patient's personal circumstances, dialysis facilities have a strong financial interest in having their patients enrolled in commercial coverage rather than public coverage (*i.e.*, Medicare and Medicaid). The agency has estimated that dialysis facilities would likely be paid "at least $100,000 more per year per patient if a typical patient enrolled in commercial coverage rather than public coverage, despite providing the exact same services to patients." 81 Fed. Reg. 90214. The agency's own comparison of data sources on ESRD spending revealed a differential of approximately $100,000 per year per patient enrolled in Medicare. *Id.* Even larger differentials were reported between commercial coverage and Medicaid coverage. *Id.*; *see also* Pls.' Ex. B ¶ 13, ECF No. 3-19 (acknowledging that "dialysis companies have an economic incentive to have dialysis patients covered by private insurance."). Dialysis facilities have so much to gain whenever a patient chooses a commercial insurance policy that the provider can come out ahead even if it makes the premium payments, a "relatively small outlay" that is dwarfed by the "much larger payment for providing an identical

set of health care services." 81 Fed. Reg. 90214-15.

Patients who must decide what coverage is best for their unique circumstances face complex choices in attempting to understand and navigate the benefits and drawbacks of health care options available to them. The main source of information and guidance for a patient, however, is often an agent of the dialysis facility. *See* Pls.' Ex. D ¶ 25 (a patient selects a health plan "following consultation with his or her social worker or other advisor provided through his or her renal care provider"). And, given that the dialysis facility stands to profit handsomely from a patient choosing commercial rather than public coverage, the provider has a large and unavoidable conflict of interest in advising patients on which plan to choose.

### C. Patient Steering

The agency issued a Request for Information in mid-2016 in light of "anecdotal reports that individuals who are eligible for Medicare and/or Medicaid benefits are receiving . . . premium and other cost-sharing assistance from a third party so that the individual can enroll in individual market plans for the provider's financial benefit." *Request for Information: Inappropriate Steering of Individuals Eligible for Medicare and Medicaid Benefits to Individual Market Plans*, 81 Fed. Reg. 57554, 57555 (Aug. 23, 2016) ("RFI"). Accordingly, the agency requested information on this subject from the public. *Id.* This was the request that led to the issuance of the Interim Rule.

In the RFI, set out in the "Proposed Rules" section of the *Federal Register*, the agency made it clear that it was exploring regulatory changes to protect consumers from inappropriate health care provider behavior, including especially any inappropriate "steering" of Medicare- and Medicaid-eligible patients to commercial plans. *Id.* at 57555-56.

The agency received an outpouring of more than 800 comments.[2] As the agency noted, many comments, including comments generated by an apparent letter campaign, were from ESRD patients expressing satisfaction with their current premium arrangements. 81 Fed. Reg. 90214. However, the agency also received disturbing comments, particularly from social work professionals, that providers may be influencing patient enrollment decisions in ways that put the providers' financial interest ahead of patient interests. *Id.* The agency addressed and quoted some of these comments at length, *id*. at 90217-18:

- Facilities engaging in systematic efforts to enroll people in the individual market, often targeting Medicaid enrollees, without assessing any personal needs. One commenter explained, "My experience was that the provider wanted anyone [who] was Medicaid only to be educated about the opportunity to apply for an individual plan. . . . The goal was 100% education, whether there was an assessed need or not. . .Valuable hours of professional interventions were taken from direct patient care concerns and diverted to this." [Ex. 8.] Another explained, "There was a list of all Medicaid patients and the insurance management team was responsible for documenting why the patient did not switch to an individual market plan." [Ex. 7.] Comments also described cases in which social worker compensation was linked to enrolling patients in individual market coverage. [*E.g.*, Exs. 5 & 6.]

- Patients are not always informed about eligibility for Medicare or Medicaid, or the benefits of those programs. For example, one social worker explained, "The patient is frequently not educated about the benefits that are available with Medicaid, i.e., transportation, dental, and other home support services)." [Ex. 6.] Another former social worker said that facility employees "may not tell patients that they could be subject to premium penalties and potentially higher out-of-pocket costs than they would have with traditional Medicare." [Ex. 2.] Another commenter said, "Enrollment counselors offer no information about Medicare eligibility to members. In several cases members were not aware that they were Medicare eligible." [Ex. 15 at 20 (Comment of America's Health Insurance Plans).]

- Patients are sometimes specifically discouraged from pursuing Medicare or Medicaid. One commenter said: "In the transplant setting I have seen patients advised to delay in securing Medicare." [Ex. 6.] Another employee at a dialysis facility relayed the story of a mother seeking a transplant for her son but being told by a dialysis facility not to enroll in Medicare. [Ex. 11.] A transplant facility employee explained "In some circumstances, the patient has been encouraged to drop their Medi-Cal (Medicaid) coverage in favor of the

[2] The comments will be among the materials in the administrative record ultimately filed with the court and are available at https://www.regulations.gov/document?D=CMS-2016-0145-0002.

individual market plan, without having a full understanding of the personal financial impact of doing so." [Ex. 1.[3]]

- Patients are unaware that a dialysis facility is seeking to enroll them in the individual market and are not informed of this fact by their health care providers. As one commenter said, "In numerous instances, these patients were already admitted at these facilities, and member interviews have found that many were unaware they had insurance, let alone who was providing it." [Ex. 13 (comment of BridgeSpan Health Company).]

- Patients are not informed about how their third party premium support is linked to continued receipt of dialysis. For example, one comment stated, "People receiving assistance don't realize that if they want a transplant the premiums will no longer get paid." [Ex. 5.]

- Facilities retaliate against social workers who attempt to disclose additional information to consumers. One commenter explained that they were "reported to upper management of [dialysis corporations] for voicing my concerns of the impact this [enrollment in the individual market] will have on patients after transplant." [Ex. 14.[4]]

- Social workers are concerned that patients' trust in health care providers is being manipulated to facilitate individual market enrollment. For example, comments explained that insurance counselors "meet often with the patients establishing a relationship of trust" before pursuing individual market enrollment. [Ex. 7.] A commenter said, "Most of us, who have some sophistication in health care coverage, are aware of how confusing it is to negotiate the information and reach the best decisions. Dialysis patients who may be less sophisticated and already highly stressed are vulnerable to being steered." [Ex. 9 (comment from nephrology social worker retired after 39 years' experience).] Another commenter vividly explained, "Patients… are in a vulnerable position when they come to a dialysis facility. I hope those of you reviewing these comments realize the power disequilibrium which exists when a patient is hooked up with needles in their arm, lifeblood running through their arms attached to a machine." [Ex. 14.]

Teri Browne, a Ph.D. who is an assistant professor at the University of South Carolina, summarized many of these concerns based on her experience including work at both Fresenius and DaVita's predecessor, Gambro. Ex. 3 at 1-2:

> Fresenius prioritized efforts to procure commercial insurance for all patients without such insurance. The [percentage] of commercially insured patients was a metric used by all dialysis

[3] *See also* Ex. 16 (comment from former DaVita social worker that "DaVita had no idea whether or not" switching a patient to private insurance would cause the patient to incur other out-of-pocket expenses like co-pays or a portion of their bill in an 80/20 PPO plan."); Ex. 1 (patients encouraged to drop Medicaid "without a full understanding of the personal financial impact").

[4] *See also* Ex. 2, Comment of Beth Witten, MSW, ACSW, LSCSW, at 2-3 (social work colleagues expressed to her worries about reprisal).

units as an important quality indicator, and constantly monitored.

> In my capacity as a kidney disease scholar . . . I have heard from countless patients and professionals that for-profit dialysis companies continue to steer patients into commercial insurance plans, despite their eligibility for Medicare and Medicaid. This is by the companies [sic] billing departments, as well as by social workers directed by their companies to do so. Tragically, this is done with no regard for the patients' existing coverage gaps (many times there are none) with Medicare and/or Medicaid, and no regard for the consequences of their efforts. I have heard from and about many patients who end up with large copayments, significantly reduced benefits, and drastically limited provider access and continuity of care because they are steered into commercial insurance plans despite their eligibility for Medicaid and/or Medicare.
>
> . . . . I have heard as recently as this week (and for many many years) horror stories from transplant workers trying to work with dialysis patients who have insurance paid for by the American Kidney Fund, and how this is a serious barrier to getting patients transplants.

### D. Hiding the Sources of Third Party Payments

The responses to the RFI also made it apparent that the sources of premium payments being made on behalf of patients were increasingly being hidden from insurers, a game that unfortunately could negatively affect continuity of coverage. As a result of the ACA, insurers in the private market are generally required to accept patients without regard to pre-existing medical conditions, including ESRD. 81 Fed. Reg. 90213. While issuers are required by regulation to accept certain third-party payments of premiums, the same regulatory requirements do not apply to dialysis facility payments of premiums (including payments made indirectly through a charity like the AKF). The agency has discouraged insurers from accepting such payments from health care providers. *See id.*; Patient Protection and Affordable Care Act: Third Party Payment of Qualified Health Plan Premiums, Interim Final Rule, 79 Fed. Reg. 15240 (Mar. 14, 2014).

The Interim Rule describes an escalating contest between third-party payers attempting to disguise their payments and insurers attempting to discover the source:

> Many issuers have provisions in their contracts with enrollees that are intended to void the contract if payment is made by someone other than the enrollee. Issuers that provided comments in response to the RFI confirmed that they do not accept certain third party payments. One comment included a list of ten states where major issuers are known to

> reject these payments when identified. Comments from health care providers and non-profits described that entities that make third party payments to issuers have attempted to disguise their payments to circumvent detection by issuers.[5] These comments also described how issuers are increasingly monitoring for and seeking to identify third party payments, and when issuers discover those payments, they are rejected. The lack of transparency around third party payments has therefore resulted in a situation in which patients are at significant and ongoing risk of losing access to coverage based on their issuer detecting payment of their premiums by parties other than the enrollee.

81 Fed. Reg. 90217; *see also* Pls.' Ex. 5 at 19 (comment by Fresenius acknowledging that AKF modified how it makes payments where insurers refuse to accept checks from AKF).

### E. Agency Response to Dialysis Facility Steering

In light of the reports of steering of patients by dialysis facilities, and the resulting risk of harm to patients, CMS concluded in the Interim Rule that prompt remedial action was necessary and that there was good cause to waive the normal requirements for full notice-and-comment rulemaking. 81 Fed. Reg. 90221. The Interim Rule puts two reforms into place. First, facilities must inform patients on a timely basis of their coverage options, including the financial risks and benefits of different plans; facilities must provide information about premium assistance; and facilities must, in effect, disclose their conflict of interest, noting both subsidies provided for enrollment in individual market health plans and the reimbursements the facilities expect to receive as a result of such subsidization. 81 Fed. Reg. 90227-28 (42 C.F.R. § 494.70). Second, facilities must disclose to issuers of individual market health plans when they are making, either directly or through another entity, payments of premiums; if they do so, they must either obtain assurance that the issuer will accept such payments or take reasonable steps to assure that such payments are not made. *Id*. at 90228 (42 C.F.R. § 494.180).

[5] The AKF also acknowledges that it "ha[s] had to change the method by which" it provides funds so as to avoid detection by insurers, switching from direct checks to sending the patient a "charitable grant" for the patient to use to pay the premium. Pls.' Ex. D, attachment A at 26.

The agency explained that the prompt action was required because the "widespread practice of third parties making payments of premiums for individual market coverage places dialysis patients at significant risk of three kinds of harms: [h]aving their ability to be determined ready for a kidney transplant negatively affected, being exposed to additional costs for health care services, and being exposed to a significant risk of a mid-year disruption in health care coverage." *Id*. at 90221. It explained that "these are unacceptable risks to patient health that will be greatly mitigated by this rulemaking, and that the delay caused by notice and comment rulemaking would continue to put patient health at risk." *Id*.

## ARGUMENT

"A preliminary injunction is an extraordinary remedy that should not be granted unless" the plaintiff shows "a substantial threat" of irreparable injury, "a substantial likelihood" of success on the merits, that the "threatened injury" to the plaintiff "outweighs the threatened harm" to the defendant, and that "granting the preliminary injunction will not disserve the public interest." *Google v. Hood*, 822 F.3d 212, 220 (5th Cir. 2016); *see also Mktg. Inv'rs Corp. v. New Millennium Bank*, 2011 WL 3157214, *1 (N.D. Tex. July 26, 2011) (same test for TRO). Relief "should only be granted when the movant has clearly carried the burden of persuasion" on all four requirements. *Anderson v. Jackson*, 556 F.3d 351, 360 (5th Cir. 2009). Plaintiffs have not met this burden.

### I. Plaintiffs Have No Likelihood of Succeeding on the Merits

Plaintiffs do not anywhere dispute that CMS has authority under the Medicare statute to promulgate the health-and-safety rules concerning dialysis treatment. They argue instead that the agency's reasoning in adopting these particular rules was arbitrary and capricious, 5 U.S.C. § 706(2)(A), and that the Interim Rule was promulgated "without observance of procedure required by law," 5 U.S.C. § 706(2)(D). They have no likelihood of succeeding on these claims.

### A. The Agency Articulated a Reasonable Explanation for the Interim Rule

The Court's review of the agency's reasons for issuing the Interim Rule will be "limited to determining whether [the agency's action] is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Palisades General Hosp. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005). This is a deferential standard of review under which the agency's action carries a presumption of regularity, *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 415-16 (1971), and the "party challenging an agency's rulemaking has the burden[.]" *Advocates for Highway Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1144 (D.C. Cir. 2005). The Court will ask only whether the agency has "examine[d] the relevant data and [has] articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, heightened deference will be owed to the agency's administration of the "complex and highly technical" Medicare program and its interpretation of any disputed statutory or regulatory provisions. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994).

The agency's explanation of the basis for the Interim Rule is more than satisfactory and will easily satisfy record review. The preamble to the rule begins by identifying a new regulatory problem created by the ACA and revealed by the comments on the RFI: dialysis facilities are steering—increasingly aggressively—beneficiaries into individual market plans (and away from Medicare) regardless of whether enrolling in such plans is in the patient's interest. 81 Fed. Reg. 90213-17. While CMS was first led to look into such steering across provider types, *id.* at 90214, its call for comments uncovered an acute health and safety problem in dialysis facilities, where steering appears to be increasingly prevalent, *id.* at 90214-15, and threatens patients in three ways.

First, steering can risk interference with a patient's ability to obtain a life-saving kidney transplant. The stability of a patient's coverage is a consideration in selecting transplant recipients,

and Medicare is more stable than individual market coverage when third parties make payments of premiums. *Id.* at 90215-16. Indeed, CMS found that steering had "in fact interfered with patients' care." *Id.* at 90216. As an example, CMS discussed the case of a family that was "given inaccurate information by a dialysis facility" and so "had to arrange other coverage on an emergency basis to obtain their child's transplant." *Id.*

Second, steering may increase the medical costs of some patients. *Id.* Individual market plans pose different cost sharing requirements than Medicaid and Medicare, and in light of the complex healthcare needs of dialysis patients, this different mix can mean much higher expenses in an individual market plan. For example, the agency noted that individual market plans often "limit access to a set of network providers that is more restrictive than what is available" in Medicare. *Id.* This means that a dialysis patient who is steered into individual market coverage with a narrow or limited network is vulnerable to surprise "balance billing" or huge out-of-network fees, whereas a Medicare beneficiary generally is not.

The third problem that CMS noted is specific to the current phenomenon of *secret* steering. The agency found that dialysis facilities currently steer individuals into, and make payments of premiums for, plans *regardless whether those plans themselves forbid third-parties to make payments of premiums*. *Id.* at 90217 ("Many issuers have provisions in their contracts with enrollees that are intended to void the contract if payment is made by someone other than the enrollee"). Meanwhile, entities that make payments of premiums for individual market health plans have attempted to disguise them from the issuers. *Id.* This puts beneficiaries in a very vulnerable position, as they wind up as a result (and perhaps unknowingly) violating their health insurance contracts. At any point in the year, the insurer might find out about the secret payments (insurers are "increasingly monitoring for and seeking to identify third party payments," *id.*),

refuse to accept the payments, and drop the patient from coverage if premiums are not paid, thus leaving the patient scrambling to find alternative coverage. *Id.* This is despite the fact that "[i]t is critically important that patients on dialysis have continuous access to health care coverage." *Id.*

Having determined that steering harms Medicare beneficiaries and that secret steering causes particular harm, CMS turned to the remedy. "In the face of harms . . . which go to essential patient safety and care in life-threatening circumstances," the agency determined that "immediate regulatory action" was necessary. *Id.* at 90218. But it held off on banning steering altogether, *id.*, while explaining that the agency will continue to "consider[]" that option because of its "concern[] . . . about the extent of the abuses reported." *Id.* Instead, for now, CMS opted to "focus[] on transparency," *id.*, adopting the two disclosure regulations in the Interim Rule at issue here while inviting additional comment. *Id.*

CMS plainly articulated a "satisfactory basis" for its decision, as summarized above. Plaintiffs' varied attacks on the agency's (1) finding that secret steering harms Medicare beneficiaries and (2) approach to remedying the problem fall far short of undermining that conclusion, so have no likelihood of succeeding when the Court reviews the agency's decision on the record. Pls.' Br. 15-19.

### 1. Plaintiffs' Attacks Do Not Undermine the Agency's Finding that Secret Steering Is a Risk to Beneficiary Health

*a. Transplant risk*: Plaintiffs first explain that they plan to attack the agency's finding that secret steering interferes with a beneficiary's transplant readiness. *Compare* 81 Fed. Reg. 90215-16 (explaining finding) *with* Pls.' Br. 22-23. But they concede most of the reasoning underlying that finding. They concede that "charitable premium assistance may sometimes be offered only during the period when a patient is receiving dialysis treatment," Pls.' Br. 15, such that facilities may cut off the premium assistance used to pay for a beneficiary's individual market coverage

after she receives a transplant. And they do not dispute that this hurts transplant readiness since "in order for a transplant center to determine that a patient is ready for a transplant, they must conclude that the individual will have access to continuous health care coverage." *Id.* at 90215.

What plaintiffs do dispute is that a beneficiary whose health insurance stands to be terminated (having been rendered unaffordable) should she receive an organ donation may fail to make alternative arrangements for post-donation coverage. Plaintiffs point out that a patient may seek out post-donation coverage under Medicare or other programs and, by lining such options up before a transplant, minimize any disruption. Pls.' Br. 15. And they point out that existing guidance calls for providers to disclose such options to patients. *Id.* Plaintiffs declare that CMS failed to consider the possibility that patients, so informed, would have the foresight to arrange for such alternative coverage options and so avoid any disruption in obtaining a transplant. *Id.* Not so.

CMS directly addressed the "[t]heoretical[]" possibility that some patients would, with the help of their providers, have the foresight to arrange alternative coverage options. It just found that this possibility did not eliminate the possibility of disruption—because not every patient and family would have this foresight: "In practice . . . patients struggle to understand their coverage options and rapidly navigate the Medicare sign-up process during a period where they are particularly sick and preparing for major surgery." 81 Fed. Reg. 90215. CMS pointed to comments emphasizing "that this is an extremely vulnerable group," the fact that many such individuals "are low income and have limited access to the resources necessary to navigate these sorts of coverage transitions," and comments demonstrating situations in which patients' confusion about "coverage both pre- and post-transplant ha[d] in fact interfered with patients' care." *Id.*

Plaintiffs' criticism of the agency's reasoning on this point boils down to this: they assume that *every* patient would perfectly navigate his available coverage options to minimize the

possibility that secret steering could interfere with his chance of receiving a transplant based solely on the fact that providers must inform patients of those options and sometimes assist patients in navigating them. Pls.' Br. 15. But CMS found, based on undisputed record evidence, that some patients would be unable to do so—and so that secret steering does threaten to interfere with patients' transplants. The agency's finding on this score was eminently reasonable.[6]

*b. Costs*: As for the agency's finding that secret steering can increase patients' liability for their own healthcare costs, plaintiffs agree that private insurance can pose both financial benefits and costs but complain that CMS "made no effort" to determine whether private insurance or Medicare coverage is financially beneficial to patients "in the aggregate." Pls.' Br. 17. That is simply incorrect: CMS concluded that for Medicaid-eligible patients—who represent half of all Medicare-eligible dialysis patients under 65—private insurance is not preferable in the aggregate.[7] As for individuals who are not eligible for Medicaid, the agency observed that there are "significant financial risks" of enrolling in the individual market rather than Medicare, while noting

[6] Plaintiffs also make various arguments that in their view private insurance can make it easier to obtain a transplant than Medicare and Medicaid. Pls.' Br. 16. This is not and does not purport to be an attack on the agency's finding that third-party premium payments risk interference by undermining the stability of an individual's coverage (because of the risk that such payments cease after transplant surgery). Defendants address plaintiffs' complaint that the agency did not consider relative advantages of private insurance in crafting a solution to this problem *infra* Part I.A.2.

[7] Plaintiffs forget the deferential nature of arbitrary and capricious review by quibbling with the agency's reasoning on this point, but their critique itself is unavailing. CMS noted that Medicaid patients face no cost sharing for Medicaid coverage but significant cost sharing for private insurance plans. 81 Fed. Reg. 90216. Although a Medicaid-eligible patient steered into private insurance for dialysis might theoretically retain her Medicaid benefits and seek to have her providers bill her Medicaid plan (at no cost sharing) rather than her private insurer (at significant cost sharing), the agency found that in such a case the beneficiary would obtain no significant benefit while bearing the risk that her ability "to coordinate multiple types of coverage" might prove imperfect. *Id.* Plaintiffs contend that Medicaid patients would "fully understand . . . how to use both forms of insurance coverage," because some health care providers sometimes assist patients with this task. Pls.' Br. 18. The agency's rejection of plaintiffs' patient-infallibility theory is both reasoned and reasonable. *See supra* Part I.A.1.c.

circumstances in which there maybe "offsetting financial benefit from individual market coverage," 81 Fed. Reg. 90216, a general point with which plaintiffs appear to agree. Pls.' Br. 18 (acknowledging contextual considerations). This is not a reason to doubt that steering into individual market plans can harm patients by exposing them to unexpected financial costs. Rather, it is a reason the agency was right to decide that each dialysis patient must be given all the relevant information at the time she makes her coverage decision. 81 Fed. Reg. 90219-20.

*c. Mid-year Disruption in Coverage*: Plaintiffs do not dispute the agency's finding that secret steering risks mid-year disruptions in coverage, or her related concern that "[i]t is critically important that patients on dialysis have continuous access to health care coverage." *Id.* Instead, plaintiffs argue that the Interim Rule will also cause some disruptions in coverage (by shedding daylight on ongoing steering activities) and fault CMS for not considering an alternative they believe would have avoided such disruptions, *i.e.*, mandating that insurers accept third party payments. This is not a reason to doubt the agency's finding that secret steering is a problem that creates a risk of mid-year disruptions in coverage. Moreover, CMS did consider the alternative plaintiffs suggest, but reasonably chose instead to adopt a disclosure rule for the time being, as explained in the next subpart.

### 2. The Agency's Decision to Address Secret Steering with Two Interim Disclosure Rules Was Not Arbitrary or Capricious

CMS properly found that secret steering poses significant risks to Medicare beneficiaries—of interference with transplant readiness, or exposure to additional costs for health care services, and of mid-year disruptions in coverage. But plaintiffs also plan to challenge on record review the agency's decision to address these harms by requiring transparency in the Interim Rule while it considers an outright prohibition. Plaintiffs' attacks on the agency's reasoning fall short, so this challenge has no chance of succeeding on the merits either.

*a. Consideration of disadvantages of "driving ESRD patients from QHPs" or other individual market plans*: Plaintiffs argue that the agency did not consider the costs of "driving ESRD patients from QHPs to Medicare/Medicaid coverage." Pls.' Br. 22. For example, Plaintiffs assert that premium assistance itself is a financial boon to patients that will be less available under the rule, *id.* at 22, and that commercial insurance can itself offer (in their view) advantages to a patient seeking a transplant that patients will not have insofar as the Interim Rule leads them to choose Medicare or Medicaid rather than commercial coverage.[8] Pls.' Br. 16. But CMS acknowledged that commercial insurance, especially when funded in part by premium assistance, can be better for patients while finding that it is often not. *See* 81 Fed. Reg. 90214 (discussing comments supporting of premium support); 81 Fed. Reg. 90216-17 (discussing possibility that private insurance could be financially advantageous as compared to Medicare or Medicaid for some enrollees). The agency's reasoning that one form of coverage is not systematically better was eminently reasonable, as was its corresponding finding that *transparency* would improve patients' ability to decide the best option for themselves while mitigating the harms of secret steering.

*b. Consideration of potential unlawful discrimination by insurers*: Plaintiffs argue that the agency did not consider the possibility that insurers who choose to respond to the disclosures

[8] It is irrelevant here, but defendants dispute many of the particular advantages that plaintiffs claim in their papers that commercial insurance can offer. For example, plaintiffs' reliance on studies finding a correlation between private insurance and transplant rates reflects a fundamental statistical error: confusing correlation with causation. *See Huss v. Gayden*, 571 F.3d 442, 459 (5th Cir. 2009) ("correlation is not causation"). Studies also show that patients at Fresenius' and Davita's *for-profit* dialysis facilities have 19% and 25% higher mortality rates, respectively, than patients at facilities operated by the leading *non-profit* dialysis company. Yi Zhang *et al.*, *The Effect of Dialysis Chains on Mortality Among Patients Receiving Hemodialysis*, 46 Health Servs. Res. 747 (June 2011). To explain that difference plaintiffs would presumably respond that this correlation does not indicate causation because for-profit facilities and non-profit facilities serve different populations: So too public and private insurance (*i.e.*, patients with private insurance may be more likely to receive a transplant because they are younger or healthier on average).

mandated by the insurer disclosure rule by refusing payments might violate the ACA's prohibitions against discrimination on the basis of disability and race. Pls.' Br. 24. But it is plaintiffs who have failed to explain in their motion how an insurer's refusal to accept payments of premiums from third parties based on a plan provision prohibiting such payments violates these authorities. The agency, moreover, emphasized that the Interim Rule did not alter issuers' obligations, including with respect to non-discrimination requirements. 81 Fed. Reg. 90220.

*c. Purported Break from Policy Set By OIG Opinion Letter*: Plaintiffs also assert that the Interim Rule reflects an unexplained change in policy from that established by an advisory opinion issued by the HHS Office of Inspector General (OIG) in 1997. Pls.' Br. 24-25. This argument is doubly flawed. First, the OIG opinion did not create a policy from which the Interim Rule could even theoretically depart. The OIG at HHS is charged with, *inter alia*, enforcing the fraud, waste, and abuse rules within the ambit of its "civil monetary penalty" authority, including section 231(h) of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). As part of its enforcement activities, OIG offers advisory opinions about whether it would seek civil sanctions under particular authorities under particular circumstances. Such opinions guarantee the providers who seek them—but no one else—will not be the subject of an enforcement action by OIG for violation of any authority they address under the particular circumstances they address. 42 C.F.R. § 1008.53. They do not set "policy" for OIG, let alone any other component of HHS, but only describe its exercise of enforcement discretion as to the subject statutes.

Consistent with its regulatory bases, 42 C.F.R. § 1008 *et seq.* ("OIG Advisory Opinions"), the OIG opinion plaintiffs cite makes very clear that it does not set OIG policy but rather offers OIG's opinion that a particular proposed arrangement would not violate the cited HIPAA provisions. *See* Pls.' Ex. 3 at ECF page 8. The opinion states that it "is applicable only to the

statutory provision specifically noted above," that it is applicable only to the requesters and "has no application" to other entities, and that the opinion "is limited in scope to the specific arrangement described in this letter." *Id.* at ECF pages 8-9. The opinion could not be more clear.

Second, even if the OIG opinion set HHS policy generally on the subject it addressed—even if it conclusively established that the particular arrangement for payment of Medigap premiums it describes complies with the cited HIPAA provision—that is not the subject that the Interim Rule addressed. The Interim Rule did not purport to address whether any particular arrangement would violate HIPAA, let alone suggest that the arrangement blessed in the OIG opinion (or any other arrangement) violates HIPAA. In fact, the cited HIPAA provision does not apply to the payments at issue here—premium payments in the individual market. 42 C.F.R. 1320a-7a(a)(5). As discussed extensively above, CMS addressed entirely distinct questions in the Interim Rule: whether secret steering threatens the health of patients and, having concluded that it does, how best to mitigate that threat. Plaintiffs do not and cannot assert that the Interim Rule reflects an unexplained change from prior agency policy on the questions it actually addressed.

*d. Consideration of Alternatives*: As a make-weight in their discussion of the agency's findings that secret steering poses a significant risk to the health of Medicare beneficiaries, plaintiffs fault the agency for not addressing such harms by mandating that insurers accept payments of premiums from third parties. Pls.' Br. 18-19. This possibility was one of several alternatives to the Interim Rule the agency considered, but CMS rejected the idea of such a mandate based on its determination that it would create countervailing distortion in the individual market. 81 Fed. Reg. 90218 n.15 ("requiring issuers to accept payments in these circumstances would destabilize the individual market risk pool"), 90226 (same). CMS reasonably decided not to adopt a solution to the secret steering problem that would have created a separate individual

market problem, so plaintiffs have no likelihood of demonstrating on record review that the agency unreasonably failed to consider this alternative.

### B. The Interim Rule Is Procedurally Sound

Plaintiffs also are unlikely to prevail on their challenge to the Interim Rule as invalid for lack of notice. The APA allows an agency to adopt a new final rule after "publish[ing] in the Federal Register" a "[g]eneral notice of proposed rule making," 5 U.S.C. § 553(b), which includes, *inter alia*, "either the terms or substance of the proposed rule or a description of the subjects and issues involved," *id.* § 553(b)(3), and "giv[ing] interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," *id.* § 553(c). This notice requirement does not apply, however, "when the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest" "and incorporates the finding and a brief statement of reasons therefor in the rules issued." *Id.* § 553(b)(B). The Medicare Act contains similar requirements. *See* 42 U.S.C. § 1395hh(b).

The Interim Rule satisfies these requirements, both because the agency reasonably found good cause for forgoing notice, and because the Interim Rule is a logical outgrowth of the August 2016 RFI, which fairly apprised interested parties that the agency would consider new conditions for coverage or conditions of participation to restrict providers' ability to manipulate patient health care coverage decisions without regard to the patient's best interest, including policies requiring providers to disclose premium assistance for individual market enrollees to insurers. While the agency continues to consider longer-term solutions to the concerning and urgent problems identified in comments on the RFI, plaintiffs received all the process to which they are entitled under the APA in advance of the Interim Rule, and any technical departure from the requirements of § 553(b) was harmless.

### 1. The Agency's Good Cause Determination Was Not Arbitrary and Capricious

After considering the public comments submitted in response to the August 2016 RFI, the agency found that existing practices in the dialysis industry posed "unacceptable risks to patient health." 81 Fed. Reg. 90221. CMS concluded that these risks "will be greatly mitigated" by the policies codified in the Interim Rule and that delaying the adoption of those policies "would continue to put patient health at risk." *Id.* "Given the risk of patient harm," the agency determined that it "would be contrary to the public interest" to postpone adoption of the rules until after the agency had published a notice of proposed rulemaking and considered and responded to the comments received. *Id.* The agency accordingly found "good cause to waive notice and comment rulemaking" for the Interim Rule, *id.*, while soliciting additional public comment on the Interim Rule and whether the agency should take further action. *See id.* at 90218-19, 90221.[9]

The Court's review of the finding of good cause to issue the Interim Rule immediately will employ the same arbitrary-and-capricious standard that will govern the Court's substantive review of the Interim Rule. *See United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011) (quoting 5 U.S.C. § 706(2)(A)); *see, e.g.*, *United States v. Reyes*, No. EP-10-CR-985-PRM, 2010 WL 2542030, at *5 (W.D. Tex. June 22, 2010). The "good cause exception 'is an important safety value to be used where delay would do real harm,'" *Am. Transfer & Storage Co. v. ICC*, 719 F.2d 1283, 1295 (5th Cir. 1983), and that standard is readily satisfied here.[10]

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[9] CMS also found good cause to make the Interim Rule effective 30 days after publication, as opposed to the 60 days required by the Congressional Review Act (CRA). *See* 81 Fed. Reg. 90221. Plaintiffs' brief does not appear to separately challenge the agency's waiver of the 60-day requirement, and such a challenge is precluded by the CRA itself. 5 U.S.C. § 805; *see Via Christi Reg'l Med. Ctr.. v. Leavitt*, 509 F.3d 1259, 1271 (10th Cir. 2007). In any event, the same analysis supports both determinations.

[10] Plaintiffs ask the Court to apply D.C. Circuit, rather than Fifth Circuit, precedent. Pls.' Br. 11. But it is well settled that "the Fifth and Eleventh Circuits have determined that the arbitrary and

The agency's finding of "good cause" to waive strict compliance with § 553(b) rested on its reasonable determination that delaying the Interim Rule would leave patients exposed to three kinds of unacceptable risk: "Having their ability to be determined ready for a kidney transplant negatively affected, being exposed to additional costs for health care services, and being exposed to a significant risk of a mid-year disruption in health care coverage." 81 Fed. Reg. 90221. These findings of real harms to patients are supported by comments submitted in response to the RFI, and hardly reflect mere "speculation" (Pls.' Br. 19) on the part of the agency.

Plaintiffs argue that because "questions of charitable donations and third-party premium assistance have long been on HHS's radar," this is "not a case in which an agency faces . . . a new or escalating threat, and invokes the good-cause exception to head off or respond to that emergency." Pls.' Br. 21 (citing "OIG's decades-old opinion as well as more recent guidance"). But plaintiffs' own declarations establish that individual market coverage became a feasible insurance option for significant numbers of dialysis patients only in 2014, when the ACA came into effect. Pls.' Ex. B ¶ 8. The agency issued the RFI in mid-2016 in light of reports of providers steering patients towards that option for the provider's financial benefit. *See* 81 Fed. Reg. 57555. And only once it reviewed the disturbing comments on the RFI did the agency recognize the need for immediate action to prevent dialysis facilities from steering their patients toward insurance options that would benefit the provider but not the patient, and to do so in time for patients to make their enrollment decisions for the coming year. *See* 81 Fed. Reg. 90221.

The agency had good cause to act as expeditiously as it did to address these problems once

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capricious standard is the appropriate standard." *United States v. Reynolds*, 710 F.3d 498, 502 (3d Cir. 2013); *accord United States v. Brewer*, 766 F.3d 884 (8th Cir. 2014). And even the D.C. Circuit defers to "factual findings and expert judgments" that underlie an agency's finding of good cause "unless such findings and judgments are arbitrary and capricious." *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 n.3 (D.C. Cir. 2014).

they came to light. *Cf. N. Am. Coal Corp. v. Dir., Office of Workers' Comp. Programs*, 854 F.2d 386, 389 (10th Cir. 1988) (explaining that "the loss or delay of medical benefits to many eligible coal miners was a real harm" that satisfied the APA's "good cause" requirement); *Nat'l Fed'n of Fed. Emps. v. Devine*, 671 F.2d 607, 610-12 (D.C. Cir. 1982) (upholding an agency's finding of good cause to postpone, without notice and comment, federal employees' period of open enrollment in health benefit plans once it became apparent that accurate information regarding rates, benefits, and other terms of coverage would not be available for timely distribution).

Finally, "[t]he interim status of the challenged rule is a significant factor" to be considered in evaluating an agency's finding of good cause to waive compliance with § 553(b). *Mid-Tex Elec. Coop., Inc. v. FERC*, 822 F.2d 1123, 1132 (D.C. Cir. 1987); *see, e.g., Am. Transfer & Storage*, 719 F.2d at 1292-97; *Coal. for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 22-23 (D.D.C. 2010). Although an agency's invitation of post-promulgation comments does not itself "excuse" non-compliance with § 553(b), Pls.' Br. 21, courts have "consistently recognized that a rule's temporally limited scope is among the key considerations in evaluating an agency's 'good cause' claim." *Mid-Tex*, 822 F.2d at 1132. That is particularly so where, as here, the agency has already engaged the public on the issues addressed in the interim rule. *See id.* at 1132-33.

**2. Any Procedural Error Would Have Been Harmless in Light of the Notice and Opportunity for Comment Provided by the RFI**

Plaintiffs' procedural challenge to the Interim Rule additionally fails because it largely ignores the public comment process that preceded and produced the Interim Rule. The August 2016 RFI, which appeared in the "Proposed Rules" section of the *Federal Register*, solicited public comment about specific steps the agency could take to protect patients from improper steering by providers and provider-affiliated organizations. *See* 81 Fed. Reg. 57554, 57556-57. Interested parties submitted over 800 comments in response, which the agency considered in issuing the

Interim Rule. *Id.* at 90214. This public process at a minimum sufficed to render harmless any departure from the statutory requirements for issuance of the Interim Rule. *See City of Arlington v. FCC*, 668 F.3d 229, 243-46 (5th Cir. 2012), *aff'd*, 133 S. Ct. 1863 (2013).

Plaintiffs claim the RFI "is no substitute for an NPRM" because it "did not set forth a proposed rule on which to comment." Pls.' Br. 21. But an agency can satisfy the requirements of the APA by issuing a notice that includes "*either* the terms or substance of the proposed rule *or a description of the subjects and issues involved*." 5 U.S.C. § 553(b)(3) (emphases added). Thus, "[t]he notice need not specifically identify every precise proposal which [the agency] may ultimately adopt as a rule." *United Steelworkers v. Schuylkill Metals Corp.*, 828 F.2d 314, 317 (5th Cir. 1987) (internal quotation omitted). "Rather, '[t]he proper test is whether the notice would fairly [apprise] interested persons of the subjects and issues the agency was considering.'" *Id.* (quoting *Am. Transfer & Storage Co. v. ICC*, 719 F.2d 1283, 1303 (5th Cir. 1983)); *see Chem. Mfrs. Ass'n v. EPA*, 870 F.2d 177, 202-03 (5th Cir. 1989).

*United Steelworkers*, for example, involved a Medical Removal Protection ("MRP") benefit provision of an occupational safety rule. 828 F.2d at 315. The agency had published a notice which "did not propose any particular MRP benefit provision," but which described the agency's position that there should be a provision requiring employers to maintain employees' earnings if they are removed from the workplace to preserve their health and requested comment on "thirteen specific issues" including "the appropriate scope" of any MRP provision. *Id.* at 318. The Fifth Circuit held that the notice's descriptions of the issues and list of questions more than sufficed to apprise interested parties that there was an issue regarding the scope of MRP benefits. *Id.*; *see also Covad Commc'ns Co. v. FCC*, 450 F.3d 528, 534, 549 (D.C. Cir. 2006).

The RFI here notified the public that the agency had "concerns about health care providers and provider-affiliated organizations steering people eligible for . . . or receiving Medicare and/or Medicaid benefits to an individual market plan for the purpose of obtaining higher payment rates." 81 Fed. Reg. 57554. The RFI expressly requested comment on certain related issues, including "changes to Medicare . . . provider enrollment requirements and conditions of participation" that might restrict providers' ability to manipulate patient enrollment in health care plans for their own benefit, and potential "policies to require Medicare . . . providers to report premium assistance . . . for individual market enrollees to . . . issuers." *Id.* at 57557. And, noting that the agency was "particularly interested in transparency around current practices," *id.* at 57556, it asked "[w]hat actions could CMS consider to add transparency to third party payments?" *Id.* at 57557.

In light of the RFI, there is no basis for plaintiffs to claim they had "no warning" (Pls.' Br. 1) that the agency might impose the conditions for coverage adopted in the Interim Rule. Among the over 800 comments submitted were comments from all plaintiffs, Pls.' Exs. 5, 7, 8; Defs.' Ex. 4, as well as AKF, Pls.' Ex. 2, and multiple groups that include plaintiffs, Pls.' Exs. 6, 9, 17. Together their comments total well over 100 pages. They address all of the issues raised in the RFI, and identify concerns about the impact that potential regulatory changes could have on both patients and providers. In particular, plaintiffs and groups representing them urged the agency not to prohibit ESRD patients from enrolling in commercial plans, to prohibit providers from advising ESRD patients to enroll in commercial plans, or to prohibit third-party premium assistance for ESRD patients enrolled in commercial plans.[11] The agency did none of those things, but adopted

[11] An association representing the facility plaintiffs, for example, expressed concern that "the results suggested by CMS (or that would follow as a logical consequence of CMS's proposals)" included "requiring individuals with ESRD to drop Exchange-based coverage and enroll only in Medicare or Medicaid, and prohibiting Marketplace plans from accepting third party payments on behalf of individuals with ESRD." Pls.' Ex. 6 at 10. Plaintiff DPC read the RFI to "suggest[] that

policies designed to promote transparency and honest disclosure by providers to both patients and issuers. The RFI adequately notified the public that the agency might take this approach, as shown by the fact that multiple parties, including plaintiffs, submitted comments (including some supportive ones) addressing the need for more transparency.[12]

In similar circumstances, the Fifth Circuit has recognized technical departures from § 553(b) to be harmless error. In *City of Arlington*, the FCC published in the Federal Register a notice requesting comment on a "Petition for a Declaratory Ruling." 668 F.3d at 244. While acknowledging that the FCC's notice was not an NPRM, the Fifth Circuit refused to "ignore" "that, after publishing the notice in the *Federal Register*, the FCC received and considered comments from dozens of interest parties, including several of the [plaintiffs]," that "[m]any of those comments raised the very issues now raised before th[e] court," and that "the FCC addressed those issues" in its decision. *Id.* at 244-45. For the same reasons, any technical sense in which the proceedings leading to the Interim Rule departed from § 553(b) would be harmless.

## II. Plaintiffs Have Not Demonstrated a Likelihood of Irreparable Harm

A preliminary injunction cannot be entered based on a mere "possibility" of irreparable

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the agency has already made up its mind" that it is "*per se* improper for a dialysis clinic to counsel a patient about any insurance option that involves a higher reimbursement for the provider." Defs.' Ex. 4, at 1, 2; *see also* Defs.' Ex. 10, at 2 (DPC press release noting that agency's RFI "strongly suggested that it may prohibit ESRD patients with exchange plans from accepting charitable assistance that helps them pay their premiums.").

[12] Plaintiff Fresenius, for example, commented that it "supports a HIPP program that is transparent" and that the "payment procedure that is most effective for our patients is one in which AKF sends premium checks directly to insurers and[,] thereby, gives insurers transparency on the source of funds." Pls.' Ex. 5 at 19. Fresenius reported, however, that "AKF has implemented different procedures"—procedures less "effective" for patients—"in some states" where insurers are "refusing to accept AKF checks." *Id.*; *see also id.* at 30 ("Greater transparency would be an effective regulatory means to address inappropriate provider or insurer behavior."). Plaintiff DPC also expressed its belief that "concerns the agency has raised could be addressed through adherence to a uniform code of conduct that requires information to be provided in a fair, accurate and impartial manner." Defs.' Ex. 4 at 4.

harm; rather, a plaintiff must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 22 (2008). The threat of irreparable injury must be "real," "substantial," and "immediate." *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983). Plaintiffs' alleged injuries from the Interim Rule are none of these things.

Plaintiffs' claim to irreparable harm flowing from the Interim Rule's patient-disclosure requirement, new 42 C.F.R. § 494.70(c), rests solely on the facility plaintiffs' professed costs of coming into compliance. *See* Pls.' Br. 10, 25. (Indeed, the patient plaintiffs concede that they have no beef with the patient-disclosure requirement; Dialysis Patient Citizens states that "If the [Interim Rule] stopped with the first part of the rule DPC would not be challenging it." Pls.' Ex. B ¶ 14.) But, as plaintiffs themselves recognize, compliance costs associated with the patient-disclosure rule will be incurred almost entirely *before* the Court rules on their motions. *See* Pls.' Ex. C ¶ 107 ("DaVita will be forced . . . to develop and implement several new compliance systems and disclosure materials and retrain many employees, *all before the IFR's January 13, 2017 effective date"* (emphasis added)); Pls.' Ex. E ¶ 58 ("In order to compile all of the information required by the IFR in the short time provided, FMCNA *has engaged* the assistance of an outside law firm because it did not believe it could meet the demand . . . when the bulk of the time occurred during the holiday season" (emphasis added)). Moreover, plaintiffs never assert that they would be so irresponsible as to cease their efforts to comply upon receipt of an 11th hour, *temporary* stay. Thus, their assertion that the patient-disclosure rule causes them irreparable harm is a non-starter, and their request for emergency relief as to that part of the Interim Rule fails for this reason alone.

As for the insurer-disclosure rule, even assuming the rule does lead fewer dialysis patients to choose to enroll in commercial coverage, plaintiffs' boldly erroneous claim that the rule therefore "exposes patients to serious and immediate health risks," Pls.' Br. 25-26, rests on their

assertion that the care available under Medicare and Medicaid is systematically worse than the care available under private insurance. *Id.* Plaintiffs offer no non-speculative support for this assertion. For example, they point to a purported shortage of Medicaid providers, but do not discuss how easy (or difficult) it is to find in-network providers under private insurance coverage. Nor do they discuss how the relative availability and quality of medical personnel under the two programs might relate to the quality of treatment provided to enrollees in one or the other program. Plaintiffs' myopic focus on access-to-care challenges in Medicare suffers from the same flaw.

Plaintiffs' two other arguments in support of their "risk to health" claim fare no better. First, the declarations they cite for this claim use heavily qualified language, revealing just how speculative an argument this is: plaintiffs are not talking about what will happen absent an injunction, they are speculating about what might theoretically happen. *See* Pls.' Ex. C ¶¶ 17, 49-50 ("Those who become uninsured *may* lose access to [] dialysis" (emphasis added)); Pls.' Ex. E ¶ 32 (offering declarant's understanding of interaction of Medicare, Medicaid, and other programs); Pls.' Ex. F ¶ 17 (speculating that individuals might become uninsured and that if uninsured those individuals "may lose access" to dialysis").[13] Second, plaintiffs point out that Medicare does not cover family members while some private insurance plans do. But again, their declarants offer rank speculation about what they believe might happen to a hypothetical family weighing its coverage options—including state and federal subsidies generally available to eligible families—without premium assistance for commercial coverage. Pls.' Ex. B ¶ 34 (offering

[13] This speculation with regard to unidentified individuals does not even suffice to support plaintiffs' standing, let alone the more demanding standards of proving irreparable harm. "When a petitioner claims associational standing, it is not enough to aver that unidentified members have been injured. Rather, the petitioner must specifically 'identify members who have suffered the requisite harm.'" *Chamber of Commerce of U.S. v. EPA*, 642 F.3d 192, 199-200 (D.C. Cir. 2011) (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009)).

declarant's understanding of how possible loss of private coverage could impact patient with family coverage); Pls.' Ex. C ¶ 55 (same); Pls.' Ex. D ¶¶ 31-32, 39-40 (same); Pls.' Ex. E ¶ 30. The fact that plaintiffs have found multiple declarants to speculate on the same subject does not overcome their failure to actually demonstrate a likelihood of irreparable harm; if anything it underscores it.

This leaves plaintiffs' assertion of irreparable *monetary* injury, which the facility plaintiffs express in terms of potential facility closures. Pls.' Br. 27-28. The insurer-disclosure rule, to be sure, could reduce plaintiffs' profits, but this does not show that there is anything more at stake for the facility plaintiffs in this case than dollars and cents. *See infra* Part III. Those plaintiffs have turned significant—and growing—profits in recent years. *See* Ron Shinkman, *The Big Business of Dialysis Care*, New England J. Med. Catalyst (June 9, 2016) (Fresenius netted more than $1 billion in after-tax profit in 2015; revenue was up 6% in first quarter of 2016). Their suggestion that the Interim Rule, while it is in effect, would force them to downsize strains credulity, and falls far short of demonstrating a "likelihood" of injury.[14]

[14] The facility plaintiffs also assert that an injunction is needed to avoid "catastrophic" economic harm, as well as reputational harm, flowing from the possibility of termination if they fail to comply with the Interim Rule. Not so. The termination provision plaintiffs cite applies to a facility that is not in "substantial compliance," 42 U.S.C. § 1395rr(g)(1); 42 C.F.R. § 488.606(a), but noncompliance with the disclosure requirements in the Interim Rule alone would not generally be a basis for a termination. A failure to comply with the new disclosure requirements without further noncompliance deficiency findings determined under other of the many Conditions for Coverage would constitute only a "standard level" deficiency for which termination does not result unless the facility fails to submit an appropriate plan of correction. 42 C.F.R. §488.28(a); *see also* section 2728B, Ch. 2, CMS State Operations Manual (SOM), Internet Only Manual Pub. 100-07A, *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c02.pdf*. And "[o]rdinarily" a provider "is expected to take the steps needed to achieve compliance" within "60 days" of notification by the state survey agency. 42 C.F.R. § 488.28(d). So a facility *actually* at risk of termination for violating the Interim Rule would have ample time to seek relief.

## III. A Preliminary Injunction or Temporary Restraining Order Would Irreparably Harm Dialysis Patients Congress Has Entrusted the Agency to Protect

Even where a plaintiff makes a "clear showing" of imminent, actual irreparable harm and that it is likely to succeed on the merits, courts "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief," *Winter*, 555 U.S. at 24, and also must consider whether the public interest weighs in favor of or against an injunction. *Id.* Because the defendants in this case are the agency and officers responsible for protecting the health and safety of Medicare beneficiaries and so represent the public interest, these two "factors merge." *Nken v. Holder*, 556 U.S. 418, 435 (2009).

As discussed, *supra* Part II, plaintiffs' claim to irreparable harm rests on claims of the financial impact of the Interim Rule. This is not a case where a business teetering on bankruptcy needs an injunction to avoid irreparable collapse, or an automotive plant needs a respite to stay in operation. The provider plaintiffs' claims of financial harms are the sort of claims *any* business could make in challenging a rule that might reduce its profits, and the patient organization plaintiffs' expectations of foregone premium subsidies for some beneficiaries is similarly a purely financial harm. Moreover, all of this money comes out of the pockets of insurers and the federal government—and the enrollees and taxpayers who ultimately fund them with their premiums and taxes. The profit increases from secret steering that plaintiffs ask the Court to guarantee are not manna from heaven: they are funded directly by private insurance carriers, many of whom receive premium tax credit and cost sharing reduction payments from the government. Plaintiffs' financial interest, then, is balanced against the interests of the private insurers—and taxpayers—from whom, by engaging in secret steering, plaintiffs hope to pad their profits.

But plaintiffs' financial interest is far from the only public interest to be weighed; the health of Medicare enrollees is also at stake. CMS found that secret steering harms Medicare enrollees in

three ways: by interfering with transplants, by imposing excess costs on them, and by creating a risk of coverage disruption in the middle of a plan year. And it found that, for the time it takes it to evaluate whether an outright ban is warranted, the disclosure rules would mitigate that risk to health.

Congress entrusted the agency to oversee dialysis facilities—and all other Medicare providers—to safeguard the health of Medicare beneficiaries. The agency became aware of a threat to patient safety, investigated, and found a pressing problem necessitating immediate action. In light of the agency's determination, based on its expertise, that the Interim Rule is necessary to safeguard beneficiaries' health, the balance of equities weighs against injunctive relief. Moreover, the timing of plaintiffs' requested injunction would exacerbate the harm to patients. Plaintiffs seek an injunction during the remaining weeks of the open enrollment period for the individual market (which ends January 31), 45 C.F.R. §§ 147.104(b)(1)(ii), 155.410(e)(2), and during much of the general enrollment period for Medicare coverage (which runs from January 1 to March 31). 42 U.S.C. 1395p(e); 42 C.F.R. 407.15(a) (Medicare Part B). If this Court were to enjoin the enforcement of the Interim Rule, ESRD patients who enroll during the end of open enrollment (when a high number of enrollees are expected to enroll[15]) following advice from their dialysis centers will not receive the important information the Rule requires regarding, among other things, coverage options and their consequences before making their enrollment decisions. And some patients who decide to enroll in Medicare Part B as a result of the Rule may only be able to enroll

[15] *See*, CMS Office of Communications, *Health Insurance Marketplaces2017 Open Enrollment Period: January Enrollment Report* (Jan. 10, 2017), https://downloads.cms.gov/files/final-marketplace-mid-year-2017-enrollment-report-1-10-2017.pdf ("In [Open Enrollment 3] (OE3), enrollment once again climbed directly in advance of the January 31 deadline; a trend expected once again during this OE.").

during the general enrollment period that runs from January 1 to March 31, 2017. *Cf.* 42 C.F.R. §§ 407.20, 407.21 (discussing limited circumstances in which "special enrollment" is possible outside this window). Medicare Part B coverage is especially critical because it covers physician and other medical services. Any delay of the implementation of the rule would therefore negatively impact enrollees' options, even if the Court ultimately upholds the agency's rule on consideration of the administrative record.

Finally, a fundamental principle weighs against emergency relief here. At bottom, plaintiffs ask the Court to bless (at least temporarily) a deception—they do not want to tell their patients or their patients' insurers about their conflicts of interest or payments of premiums.[16] But they forget that injunctive relief is equitable relief, and "[n]othing is more abhorrent to equity than deceitful appearances covering secret preferences." *In re Beckhause*, 177 F. 141, 145 (7th Cir. 1910).

## CONCLUSION

The Court should deny plaintiffs' motion for emergency relief.[17]

Dated: January 11, 2017

Respectfully submitted,

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/s/ Joel McElvain

[16] Some facilities also discouraged their own employees from sharing their concerns during the agency's comment period, and penalized employees who raised concerns about steering. *See* Defs.' Ex. 17; Defs.' Ex. 14 at 1, 5, 6; Defs.' Ex. 2 at 2-3. Furthermore, undisclosed steering activities raise questions of violations of state and federal law. *See* Reed Abelson & Katie Thomas, *United Healthcare Sues Dialysis Chain Over Billing*, N.Y. Times (July 1, 2016).

[17] Should the Court conclude that injunctive relief is appropriate as to any part of the Interim Rule (it should not do so), it should enjoin only that part. *See K-Mart Corp. v. Cartier*, 486 U.S. 281, 294 (1988) (court should sever where "there is no indication that the regulation would not have been passed but for its inclusion"); *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) ("injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief").

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## CERTIFICATE OF SERVICE

I hereby certify that on January 11, 2017, I filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record who are deemed to have consented to electronic service.

/s/ Joel McElvain
JOEL McELVAIN